

## **BUSINESS ASSOCIATE AGREEMENT**

This BUSINESS ASSOCIATE AGREEMENT (“Agreement”) effective as of the later-dated signature hereto (“Effective Date”), identifies and clarifies the relationship and responsibilities of FUJIFILM Medical Systems U.S.A., Inc. a New York corporation having its principal offices at 81 Hartwell Avenue, Suite 300, Lexington, MA 02421 (“FMSU”), hereby acting as the business associate and \_\_\_\_\_, a \_\_\_\_\_ having its principal offices at \_\_\_\_\_ (the “Covered Entity”), hereby acting as the covered entity.

**WHEREAS**, the Covered Entity is subject to the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d – 1320d-8 (“HIPAA”), as amended from time to time, and is required to safeguard individually identifiable health information the Covered Entity uses, discloses, maintains, or otherwise accesses (hereinafter “protected health information” or “PHI”) in accordance with the requirements HIPAA establishes and also the requirements set forth in the Health Information Technology Act for Economic and Clinical Health Act and any regulations promulgated thereunder (the “HITECH Act”); and

**WHEREAS**, the Covered Entity and FMSU have entered into one or more agreements (“Underlying Agreement(s)”) under which FMSU receives, accesses, uses or in some way obtains PHI.

**NOW THEREFORE**, for and in consideration of the mutual premises, conditions and covenants herein contained, the parties hereto agree as follows:

**1. DEFINITIONS.** Terms used, but not otherwise defined, in the Agreement shall have the same meaning as those terms in the federal Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164 (the “Privacy Rule”); the Breach Notification Rule, 45 C.F.R. 164 Subpart D (“Breach Notification Rule”) and the federal Security Standards, 45 C.F.R. Parts 160 and 164 (the “Security Standards”), as they may be amended from time to time.

### **2. OBLIGATIONS AND ACTIVITIES OF FMSU WITH RESPECT TO PROTECTED HEALTH INFORMATION**

#### **2.1 Obligations Regarding Uses and Disclosures of PHI.**

- (a) FMSU agrees to not use or disclose PHI other than as permitted or required by this Agreement, including without limitation, Section 2.2, or as Required By Law.
- (b) FMSU agrees to use appropriate safeguards and comply with Subpart C of 45 C.F.R. 164 with respect to Electronic PHI, to prevent use or disclosure of PHI other than as provided for by this Agreement.

- (c) FMSU agrees to timely report to the Covered Entity, any use or disclosure of PHI not provided for by this Agreement of which it becomes aware.
- (d) FMSU agrees to ensure that any subcontractor to whom it provides PHI received from, or created or received by FMSU on behalf of the Covered Entity, agrees to restrictions and conditions at least as protective of the PHI as the terms of this Agreement.
- (e) FMSU agrees to provide timely access to PHI in a Designated Record Set to the Covered Entity upon the written request of the Covered Entity in order to meet the requirements under 45 C.F.R. 164.524. In the event FMSU receives a request directly from an Individual for access to PHI in a Designated Record Set, FMSU will provide timely written notice to the Covered Entity of such request.
- (f) FMSU agrees to make timely amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. 164.526 at the request of the Covered Entity. In the event FMSU receives a request directly from an Individual for an amendment to PHI in a Designated Record Set, FMSU agrees to provide timely written notice to the Covered Entity of such request.
- (g) FMSU agrees to make internal practices, books, and records which relate to the use and disclosure of PHI received from, or created or received by FMSU on behalf of, the Covered Entity available to the Secretary of the Department of Health and Human Services, in a reasonable time and manner or as designated by the Secretary, for purposes of the Secretary determining compliance with the Privacy Rule.
- (h) FMSU agrees to document such disclosures of PHI and information related to such disclosures as would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. 164.528.
- (i) FMSU agrees to timely provide the Covered Entity information collected in accordance with 2.1(h) above of this Agreement, to permit the Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. 164.528. In the event FMSU receives a request directly from an Individual for an accounting of disclosure(s) of PHI by FMSU, FMSU agrees to provide timely written notice of such request to the Covered Entity.
- (j) To the extent FMSU agrees explicitly in writing to carry out any of the Covered Entity's obligation(s) under Subpart (E) of 45 C.F.R. 164, FMSU agrees to comply with the requirements of such Subpart (E) that apply to the Covered Entity in the performance of such obligation(s).



- 2.2 Permitted General Uses and Disclosures by FMSU. FMSU may use or disclose PHI (i) for the purpose of performing services under the Underlying Agreement; (ii) for the proper management and administration of FMSU; (iii) to carry out the legal responsibilities of FMSU; and (iv) as Required By Law, if such use or disclosure of PHI would not violate HIPAA, the Privacy Rule or the Security Standards if done by the Covered Entity or the minimum necessary policies and procedures of the Covered Entity. In addition, FMSU may de-identify images or other data that contain PHI in accordance with 45 C.F.R. § 164.514 of HIPAA, and may use and disclose such de-identified images or other data for any purpose not prohibited by applicable law.
- 2.3 Notification Obligations Regarding Breaches of Unsecured PHI. FMSU agrees to report to the Covered Entity any Breach of Unsecured Protected Health Information without unreasonable delay and in no case later than 60 calendar days after the Discovery of such a Breach of Unsecured Protected Health Information, as those terms are defined in the Breach Notification Rule. FMSU's notice to the Covered Entity shall include the applicable elements as set forth at 45 C.F.R. 164.410(c).

### **3. OBLIGATIONS OF THE COVERED ENTITY**

- 3.1 Notification of Privacy Practices and Restrictions.
- (a) The Covered Entity shall notify FMSU of any limitation(s) in the Covered Entity's Notice of Privacy Practices in accordance with 45 C.F.R. 164.520, to the extent that such limitation may affect FMSU's use or disclosure of PHI.
  - (b) The Covered Entity shall notify FMSU of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect FMSU's use or disclosure of PHI.
  - (c) The Covered Entity shall notify FMSU of any restriction to the use or disclosure of PHI that the Covered Entity has agreed to in accordance with 45 C.F.R. 164.522 to the extent that such restriction may affect FMSU's use or disclosure of PHI.
- 3.2 Permissible Request by the Covered Entity. The Covered Entity shall not request FMSU to use or disclose PHI in any manner that would not be permissible under the Privacy Rule or Security Standards if done by the Covered Entity; except for the management and administrative and legal responsibilities of FMSU under this Agreement.
- 3.3 Minimum Necessary Disclosure. The Covered Entity shall provide to FMSU only the "minimum necessary" PHI (as described in 45 C.F.R. 164.502(b)) required for FMSU to perform its obligations under the Underlying Agreement(s).



#### 4. TERM AND TERMINATION

- 4.1 Term. This Agreement shall be effective as of the Effective Date and shall terminate upon the termination of the Underlying Agreement(s).
- 4.2 Termination for Cause. Upon the Covered Entity's knowledge of a material breach of this Agreement by FMSU, the Covered Entity shall either:
- (a) Provide an opportunity for FMSU to cure the breach or end the violation and terminate this Agreement if FMSU does not cure the breach or end the violation within the time specified by the Covered Entity; or
  - (b) Immediately terminate this Agreement if FMSU has breached a material term of this Agreement and cure is not possible.
- 4.3 Effect of Termination.
- (a) Except as provided in paragraph 4.3(b) below, upon termination of this Agreement for any reason, FMSU shall return or destroy all PHI received from the Covered Entity or created or received by FMSU on behalf of or at the direction of the Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors of FMSU. FMSU shall retain no copies of the PHI.
  - (b) In the event that FMSU determines that returning or destroying the PHI is infeasible, FMSU shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. When return or destruction of PHI is infeasible, FMSU shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destructions infeasible, for as long as FMSU maintains such PHI.

#### 5. MISCELLANEOUS

- 5.1 Regulatory References. A reference in this Agreement to a section in the Privacy Rule, the Security Standards or the Breach Notification Rule means the section as in effect or as amended.
- 5.2 Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Covered Entity and FMSU to comply with the requirements of HIPAA.
- 5.3 Survival. The respective rights and obligations of FMSU under Paragraphs 4.3 of this Agreement shall survive the termination of this Agreement.
- 5.4 Interpretation. Any ambiguity in this Agreement shall be resolved to permit the Covered Entity and FMSU to comply with HIPAA and the implementing regulations, as they may be amended from time to time.



- 5.5 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and the respective successors and assigns of the parties, any rights, remedies, obligations or liabilities whatsoever.
- 5.6 Limitation of Liability. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY) OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

We have carefully reviewed this contract and agree to and accept its terms and conditions.

**COVERED ENTITY**

\_\_\_\_\_  
By (Signature)

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

**FUJIFILM Medical Systems U.S.A., Inc.**

\_\_\_\_\_  
By (Signature)

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

